|   | Application No.  | Applicant(s)   |
|---|--|--|
| Notice of Allowability  | 09/750,609   | ROBERTSON ET AL.   |
|   | Examiner   | Art Unit   |
|   | Suryaprabha Chunduru   | 1637   |
| The MAILING DATE of this communication apperall claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI  | (OR REMAINS) CLOSED in this a<br>or other appropriate communication<br>GHTS. This application is subject | pplication. If not included on will be mailed in due course. <b>THIS</b> |
| 1. This communication is responsive to <u>9/22/2005</u> .   |  |  |
| 2. The allowed claim(s) is/are <u>4-12,14,15,17,80 and 81</u> .   |  |  |
| <ol> <li>Acknowledgment is made of a claim for foreign priority unapplication.</li> <li>All b) Some* c) None of the:         <ol> <li>Certified copies of the priority documents have</li> <li>Certified copies of the priority documents have</li> <li>Copies of the certified copies of the priority documents have</li> <li>International Bureau (PCT Rule 17.2(a)).</li> </ol> </li> <li>* Certified copies not received:</li> <li>Applicant has THREE MONTHS FROM THE "MAILING DATE"</li> </ol>  | been received. been received in Application No. cuments have been received in this                       | s national stage application from the                                    |
| noted below. Failure to timely comply will result in ABANDONM THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.  4. A SUBSTITUTE OATH OR DECLARATION must be submit INFORMAL PATENT APPLICATION (PTO-152) which give   | itted. Note the attached EXAMINE   |  |
| <ul> <li>5. CORRECTED DRAWINGS ( as "replacement sheets") must be submitted. <ul> <li>(a) including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached</li> <li>1) hereto or 2) to Paper No./Mail Date</li> <li>(b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date</li> <li>Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).</li> </ul> </li> <li>6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.</li> </ul> |  |  |
| Attachment(s)  1. Notice of References Cited (PTO-892)  2. Notice of Draftperson's Patent Drawing Review (PTO-948)  3. Information Disclosure Statements (PTO-1449 or PTO/SB/0 Paper No./Mail Date  4. Examiner's Comment Regarding Requirement for Deposit of Biological Material  | 6. Interview Summar<br>Paper No./Mail D<br>7. Examiner's Amend<br>8. Examiner's Staten                   | ate  |

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## **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been

timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR

1.114. Applicant's submission filed on September 22, 2005 has been entered.

2. Applicants' response and amendment filed along with RCE on September 22, 2005 is

considered. Currently Claims 1-17, 80-81 are pending. Claims 4-5, 8,14, 15 are amended. New

claim 81 is added. Claims 18-79 are canceled.

3. An examiner's amendment to the record appears below. Should the changes and/or additions

be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To

ensure consideration of such an amendment, it MUST be submitted no later than the payment of

the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with

Arles A. Taylor, Jr. on January 18,2006.

Please amend the claims as follows:

Cancel claims 1-3, 13 and 16.

Amend claims 11 and 17as follows:

The claims 11 and 17 should read as follows:

Claim 11. The method of claim 4 or 5, wherein the polymorphism is detected by

sequencing a target nucleic acid in the nucleic acid sample from the subject.

Claim 17. The method of claim 4, wherein the subject is a human subject.

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4. The following is an examiner's statement of reasons for allowance:

Claims 4-12, 14-15, 17, 80-81 are allowed.

The present invention is drawn to a method of screening for susceptibility to sub-optimal norepinephrine (NE) transport resulting in decreased NE clearance in a subject comprising detection of a polymorphism of NE transporter gene in a biological sample, said method comprising detection of a G to C transversion within NE trasporter exon 9 (includes 129-257 of SEQ ID No. 15) and the presence of the polymorphism indicates the susceptibility of the subject to sub-optimal NE transport resulting in decreased NE clearance and encodes a NE transporter polypeptide having proline moiety at AA 457 of SEQ ID No. 1. Further said sub-optimal NE clearance is characterized as a susceptibility to orthostatic intolerance. The closest prior art Jacob et al. in view of Johnson et al. teach a polymorphism in NE transporter gene however the art is silent with regard to the polymorphism comprising G to C transversion in exon 9 of NE transporter gene and its correlation to decreased NE clearance and its association to orthostatic intolerance. Thus the instant invention was not taught or obvious over the closest prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru

Patent Examiner Art Unit 1637

January 23, 2006.